JAN 1 0 2002

K013515

510(k) SUMMARY
as required per 807.92(c)

Submitters Name, Address:

Siemens Medical Systems, Inc.
Electromedical Systems Group, PCS
Danvers, MA 01923
Tel: (978) 907-7500
Fax: (978) 750-6879
Official Correspondent: Connie Hertel, Director
Quality Assurance & Regulatory Affairs
Contact person for this submission: Penelope H. Greco
Date submission was prepared: October 18, 2001

Trade Name, Common Name and Classification Name:

A. Trade Name:
Siemens INFINITY EXPLORER

B. Common Name, Classification Name, Class and Regulation Number:

Common Name	Classification Number	Class	Regulation Number
Display, Cathode-ray tube, Medical	DXJ	II	21 CFR 870.2450
System, Network and Communication, Physiological Monitors	MSX		
Computers and Software, Medical	LNX		
System, Digital Image Communications, Radiological	LMD	1	21 CFR 892.2020

Predicate Device Identification:

K970348	SC 9000 / SC 9015 Series Surgical Display Controller
K955059	SC3000 MULTIVIEW WorkStation and Remote Display

Other relevant submissions

K980882	SC 7000 / SC 9000XL
K983632	SC 8000
K003243	INFINITY Modular Monitors Modifications
K010938	*syngo* Multimodality Workstation

Device Description:
The INFINITY EXPLORER is a critical care workstation that acts as a display for physiological parameters received from an INFINITY patient monitor (SC 7000/SC 8000/ SC 9000XL). INFINITY EXPLORER provides the user with a visual indication of alarms for those parameters displayed (audio alarming and flashing visual indications are provided on the INFINITY patient monitor screen).

INFINITY EXPLORER utilizes the *syngo* (510k K010938) software platform and user interface common to other Siemens Medical modalities. INFINITY EXPLORER with *syngo* software is capable of displaying DICOM images retrieved from a *syngo* compatible DICOM server. The INFINITY EXPLORER Images Task Card provides access to DICOM images.

Intended Use:
The INFINITY EXPLORER is a critical care workstation intended to display physiological parameters received from INFINITY Modular Monitors and to visually display alarm data for those parameters. The device is capable of displaying DICOM images received over a hospital information system.

Assessment of non-clinical performance data for equivalence:
Substantially equivalent (Section S)

Assessment of clinical performance data for equivalence:
Substantially equivalent (Section U)

Biocompatability:
Not applicable

Sterilization:
Not applicable

Standards and Guidance: Section R

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Table of Device Similarities and differences to legally marketed device

Manufacturer	**Legally Marketed Device Olympus Communications Network, SC 3000 Workstation and Remote Display (MultiView WorkStation and INFINITY Network) Siemens Medical Systems**	**Legally Marketed Device SC 9000 / 9015 Bedside Monitoring System Surgical Display Controller**	**New Device INFINITY EXPLORER Same**	**Explanation of Differences**
510(k)	K955059	K970348	To be determined	
Intended Use	To act as a communications network, central monitoring device, and remote display for Siemens Patient Monitoring Systems and recorders	The Surgical Display Controller is to display SC 9000 / 9015 Bedside Monitor functions on a Siemens 15" Remote Display or on a standard video display	The INFINITY EXPLORER is a critical care workstation intended to display physiological parameters received from INFINITY Modular Monitors (SC 7000 / SC 9000XL / SC 8000) and to visually display alarm data for those parameters. The device is capable of displaying DICOM images received over a hospital information system.	The SC 7000 / SC 9000XL (K980882) and SC 8000 with Advanced Communication Option, 510(k) K990563 included the Surgical Display Controller
Intended Environment	In a healthcare environment where patient care is provided by healthcare professionals.	Wherever the Siemens SC 9000 / 9015 Bedside Monitor is used	Wherever a Siemens INFINITY Monitor (SC 7000 / SC 8000 / SC 9000XL) is used	

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Manufacturer	**Legally Marketed Device Olympus Communications Network, SC 3000 Workstation and Remote Display (MultiView WorkStation and INFINITY Network) Siemens Medical Systems**	**Legally Marketed Device SC 9000 / 9015 Bedside Monitoring System Surgical Display Controller**	**New Device INFINITY EXPLORER Same**	**Explanation of Differences**
510(k)	K955059	K970348	To be determined	
Intended Population	Not connected to patients	Same	Same	Although not connected directly to patients, the INFINITY EXPLORER is intended to be used with the same patient populations as the INFINITY Modular Monitors, Adult, Pediatric, and Neonatal.
Display	Displays data received from the patient monitor and the INFINITY Telemetry System via the INFINITY Network	User selectable. Independent from bedside monitor's primary display	Same as K970348	
Audible Alarm	Yes	No	No	
Visual Alarm	Yes	No	Yes	
Testing	Verification and validations tests have been performed which indicate that the INFINITY EXPLORER is as safe and effective as the predicate devices			

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 1 0 2002

Ms. Penelope H. Greco
Regulatory Submissions Manager
Siemens Medical Systems, Inc.
Electromedical Systems Group, PCS
16 Electronics Avenue
Danvers, MA 01923

Re: K013515
Trade Name: Infinity Explorer
Regulation Number: 21 CFR 870.2300
Regulation Name: Cardiac Monitor
Regulatory Class: Class II (two)
Product Code: MSX
Dated: October 18, 2001
Received: October 22, 2001

Dear Ms. Greco:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Bram D. Zuckerman, M.D.
Acting Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K013515

Device Name: Siemens INFINITY EXPLORER

Indications for Use:

This device is capable of displaying physiological parameters received from INFINITY monitors (SC 7000, SC 8000, SC 9000XL) and visually displaying alarm data for those parameters. The device is capable of displaying DICOM images received over a hospital information system.

The device is intended to be used in the environment where patient care is provided by Healthcare Professionals, i.e. physicians, nurses, and technicians, trained on the use of the device, who will determine when use of the device is indicated, based upon their professional assessment of the patient's medical condition.

The device is intended for use with the adult, pediatric and neonatal populations.

MRI Compatibility Statement:
The Siemens INFINITY EXPLORER is not compatible for use in a MRI magnetic field.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Division of Cardiovascular & Respiratory Devices
510(k) Number K013515